

# Exhibit H

Denise Elser, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

-----	)	Master File No.
IN RE: ETHICON, INC.,	)	2:12-MD-02327
PELVIC REPAIR SYSTEM	)	
PRODUCTS LIABILITY	)	MDL 2327
LITIGATION	)	
-----	)	JOSEPH R. GOODWIN
	)	U.S. DISTRICT JUDGE
LAURA WAYNICK, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	Case No.
-vs-	)	2:12-cv-01151
	)	
ETHICON, INC., ET AL.,	)	
	)	
Defendants.	)	
	)	
-----	)	

The deposition of DENISE ELSER, M.D., called by the Plaintiffs for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and a Certified Shorthand Reporter of the State of Illinois, at the Le Meridien Chicago - Oakbrook Center, Discovery Room, 2100 Spring Road, Oak Brook, Illinois, on March 31, 2016, commencing at 7:22 p.m.

Denise Elser, M.D.

Page 38	Page 40
<p>1 front of you?</p> <p>2 A. Yes.</p> <p>3 Q. Can you turn to page 31 of that</p> <p>4 deposition, specifically lines 13 through 18.</p> <p>5 MS. SMITH: Do you mind telling me the</p> <p>6 page again?</p> <p>7 MR. FAES: Page 31, lines 13 through 18.</p> <p>8 BY MR. FAES:</p> <p>9 Q. Have you read that testimony, Doctor?</p> <p>10 A. Yes.</p> <p>11 Q. Does that testimony change your answer</p> <p>12 in any way about what Dr. Hurford knew about the</p> <p>13 risk of chronic pain with the TVT device and</p> <p>14 procedure at the time of Ms. Waynick's surgery in</p> <p>15 2000?</p> <p>16 A. Well, sorry. I can't just answer yes or</p> <p>17 no.</p> <p>18 It makes it more confusing because here</p> <p>19 he says he knows that there can be pain after</p> <p>20 surgery but not specific to the TVT. And here he</p> <p>21 says he was unaware there could be chronic pain</p> <p>22 associated with the TVT, but he knows there can be</p> <p>23 chronic pain after surgery.</p> <p>24 Q. Doctor, let me ask you a different</p>	<p>1 stop and I am going to make some calls because it's</p> <p>2 not.</p> <p>3 THE WITNESS: Could I have the question back</p> <p>4 (WHEREUPON, the record was read</p> <p>5 by the reporter as requested as</p> <p>6 follows: Q. Would you agree that</p> <p>7 marketing the TVT device as having</p> <p>8 a risk of acute and/or chronic pain</p> <p>9 is more accurate than marketing it</p> <p>10 without having that information in</p> <p>11 the IFU?)</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes, it's more accurate to say there can</p> <p>14 be acute or chronic pain but with surgery, and this</p> <p>15 is something physicians know. It does not need to</p> <p>16 be in an IFU.</p> <p>17 MR. FAES: Object and move to strike after the</p> <p>18 answer ending with the word "pain."</p> <p>19 BY MR. FAES:</p> <p>20 Q. Doctor, do you believe it was</p> <p>21 unnecessary to have "acute and/or chronic pain" in</p> <p>22 the IFU that was provided to Dr. Hurford in</p> <p>23 November of 2000?</p> <p>24 MS. SMITH: All right. We are going to take a</p>
Page 39	Page 41
<p>1 question.</p> <p>2 Doctor, if Ethicon had marketed the TVT</p> <p>3 device as having a risk of acute and/or chronic</p> <p>4 pain rather than omitting that information from</p> <p>5 their IFU, do you think that might have changed the</p> <p>6 perception of the TVT device among the medical</p> <p>7 community and thus might have changed Dr. Hurford's</p> <p>8 decision about whether or not to use the device?</p> <p>9 MS. SMITH: Object to form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Again, it's speculation. I doubt it.</p> <p>12 BY MR. FAES:</p> <p>13 Q. Would you agree that marketing the TVT</p> <p>14 device as having a risk of acute and/or chronic</p> <p>15 pain is more accurate than marketing it without</p> <p>16 having that information in the IFU?</p> <p>17 MS. SMITH: This is -- I'm truly shocked but</p> <p>18 this is not case-specific.</p> <p>19 MR. FAES: I disagree.</p> <p>20 MS. SMITH: I don't see how it could be.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Could I have the --</p> <p>23 MS. SMITH: Object to form. I'm going to let</p> <p>24 it go just a little bit but then we are going to</p>	<p>1 break because I need to -- to me this is very</p> <p>2 general and I need to get guidance on how to handle</p> <p>3 it.</p> <p>4 MR. FAES: Well, just for the record I've been</p> <p>5 using Dr. Waynick and Dr. Hurford in almost every</p> <p>6 question related to the IFU. I don't see how I can</p> <p>7 do case-specific discovery without relating her</p> <p>8 general opinions to the case-specific facts that</p> <p>9 are front of us.</p> <p>10 I am almost done with this line of</p> <p>11 questioning but if you need to take a break and</p> <p>12 make a call.</p> <p>13 MS. SMITH: If you're almost done.</p> <p>14 MR. FAES: I'd like three more questions.</p> <p>15 MS. SMITH: Is that a lawyer three? Let's see</p> <p>16 because --</p> <p>17 BY MR. FAES:</p> <p>18 Q. Do you need the question read back to</p> <p>19 you, Doctor, or do you recall what it was?</p> <p>20 A. I think you said do I believe it was</p> <p>21 unnecessary to have --</p> <p>22 Q. Yes.</p> <p>23 A. -- that in the IFU. Yes.</p> <p>24 Q. Do you believe it was unnecessary to</p>

11 (Pages 38 to 41)

Denise Elser, M.D.

Page 42	Page 44
<p>1 have the word "dyspareunia" in the IFU at the time</p> <p>2 of Ms. Waynick's surgery in November of 2001?</p> <p>3 A. Yes.</p> <p>4 Q. But you know that both of those items</p> <p>5 are in the IFU currently, correct?</p> <p>6 A. Yes.</p> <p>7 Q. Do you believe that Ethicon has put</p> <p>8 unnecessary risks in their IFU?</p> <p>9 MS. SMITH: Currently?</p> <p>10 BY THE WITNESS:</p> <p>11 A. Do they -- yes, I think a lot of the</p> <p>12 things in the IFU are unnecessary and most good</p> <p>13 surgeons do not rely on the things listed in the</p> <p>14 IFU to show complications unless it's something</p> <p>15 truly unique to the device or something you need to</p> <p>16 learn for the first time.</p> <p>17 Surgeons who do incontinence surgery</p> <p>18 know there is a risk of acute and chronic pain.</p> <p>19 Surgeons who put a foreign body in any part of the</p> <p>20 body know there can be a risk of acute and chronic</p> <p>21 pain.</p> <p>22 MR. FAES: I'm going to mark this Exhibit 8</p> <p>23 and I have one question about it and then I'm going</p> <p>24 to move on.</p>	<p>1 November of 2001 which do you feel would have been</p> <p>2 the more appropriate IFU to give to Dr. Hurford,</p> <p>3 Exhibit No. 7 or Exhibit No. 8?</p> <p>4 A. I can't answer yes or no because I think</p> <p>5 it doesn't matter.</p> <p>6 Q. Okay. Doctor, would you agree that</p> <p>7 Dr. Wasserman diagnosed Ms. Waynick with vaginal</p> <p>8 bleeding, pain and granulation tissue at an office</p> <p>9 visit on July 13, 2001?</p> <p>10 A. I agree he diagnosed her with those</p> <p>11 things. I just want to look at the date because I</p> <p>12 don't have -- I don't know that.</p> <p>13 I should be close to it.</p> <p>14 Can you tell me the date again, please,</p> <p>15 because I think you said 2001.</p> <p>16 Q. Yes. Doctor, would you -- if I did, I</p> <p>17 didn't mean to say that, so I will restate that.</p> <p>18 MS. SMITH: You did say that.</p> <p>19 BY THE WITNESS:</p> <p>20 A. See why I had to check the date.</p> <p>21 BY MR. FAES:</p> <p>22 Q. Don't just agree with everything I say,</p> <p>23 Doctor.</p> <p>24 Would you agree, Doctor, that</p>
Page 43	Page 45
<p>1 MS. SMITH: What is it?</p> <p>2 MR. FAES: It's the 2015 IFU. Well, two</p> <p>3 questions because I'm going to ask her.</p> <p>4 (WHEREUPON, a certain document was</p> <p>5 marked Elser Deposition Exhibit</p> <p>6 No. 8, 2015 Gynecare TVT IFU.)</p> <p>7 BY MR. FAES:</p> <p>8 Q. Doctor, I have handed you what's marked</p> <p>9 Exhibit 8. Do you know what that is?</p> <p>10 A. It's the Gynecare TVT IFU dated 1/2015.</p> <p>11 Q. So, I just have one question with regard</p> <p>12 to that exhibit.</p> <p>13 Which do you believe is the more</p> <p>14 appropriate IFU, Exhibit No. 7 or Exhibit No. 8?</p> <p>15 MS. SMITH: All right. Now that is about as</p> <p>16 general as it gets. So, we are going to take a</p> <p>17 break because I was told specifically --</p> <p>18 MR. FAES: Let me -- I will withdraw that</p> <p>19 question.</p> <p>20 MS. SMITH: Let me finish --</p> <p>21 MR. FAES: I will withdraw that question. Let</p> <p>22 me ask a different question.</p> <p>23 BY MR. FAES:</p> <p>24 Q. At the time of Ms. Waynick's surgery in</p>	<p>1 Dr. Wasserman diagnosed Ms. Waynick with vaginal</p> <p>2 strike that.</p> <p>3 Doctor, would you agree that</p> <p>4 Dr. Wasserman diagnosed Ms. Waynick with vaginal</p> <p>5 bleeding, pain and granulation tissue at an office</p> <p>6 visit on July 13, 2011?</p> <p>7 A. I have trouble answering that. Can I</p> <p>8 explain?</p> <p>9 Q. First if you can answer it yes or no or</p> <p>10 you can't answer it yes or no and then you can</p> <p>11 provide an explanation, please.</p> <p>12 A. Yes, I can't answer it yes or no.</p> <p>13 Q. Why is that?</p> <p>14 A. Because he says here, "She has suffered</p> <p>15 injury and complications from the vaginal mesh, has</p> <p>16 bleeding, pain and granulation tissue," but that's</p> <p>17 the subjective. So, that would mean this is what</p> <p>18 the patient is saying. So, that means he is not</p> <p>19 diagnosing it.</p> <p>20 And if we look to the visit before that,</p> <p>21 on June 29, 2011, here he is diagnosing granulation</p> <p>22 tissue issue.</p> <p>23 Q. So, would you agree that Dr. Wasserman</p> <p>24 diagnosed Ms. Waynick with granulation tissue in an</p>

12 (Pages 42 to 45)